A New Surgical Approach to Vasodilating Therapy in Peripheral Occlusive Vascular Disease

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Summary

Intraarterial infusion of vasoactive substances for ischemic conditions of the lower limbs in chronic occlusive arterial disease has been shown to be an effective therapeutic measure. Up to now there has been the dilemma of a limited therapy duration, because of the frequent and necessarily repeated single punction maneuvers. Percutaneously introduced longer lasting catheters do not present a reasonable alternative because of their comparatively short functioning time. The implantation of a subcutaneously implaced port system with introduction of the infusion tube into a side branch of the femoral artery however provides an uncomplicated and permanent arterial access of low risk. The punctions of the catheter system are safe and can be done quickly and easily with minimal burden on the patients only. By using this device even longterm and/or repeated intermittent arterial infusions for the treatment of chronic lower limb ischemia are made possible.

Introduction

There is no doubt that intraarterial administration of vasodilating substances has been established as an important remedy within the therapy of occlusive peripheral arterial disease. Especially in progressive stages there are certain well proven benefits of this kind of treatment. Since the introduction of *Prostaglandin* E_1 by BERGSTRÖM in 1968[1] as a potent vasodilating agent and its intraarterial infusion into the femoral artery by CARLSON in 1973[5] there has been a great number of communications about the beneficial effects of this treatment[3,4,6,7,10,12,18,20] The reports claim the healing of ischemic ulcers as well as a significant reduction of rest pain in Grade Ⅲ and Ⅳ of FONTAINE's classification.

However in many cases the severity of the disease requires a number of repeated therapies, which have to be performed over a longer period of time. The practical limitations of such

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therapeutic measures have been the actual obstacles to prevent a broader and more intense use of intraarterial infusions. The necessity of numerous repeated arterial punctions causes a lot of undesired side effects, presenting the following main disadvantages:

A) mechanical damage of the vascular wall by repeated punction maneuvers
B) accompanying risk of arterial thrombosis or embolism
C) increasing hematoma development in the punction area following the repeated removal of the iniection needles
D) accompanying danger of infection
E) increasing pain of the patient after continuous cannulation of the femoral artery over a longer period.

To avoid these disadvantages of repeated intraarterial infusions we developed a new surgical approach to this kind of treatment, using a subcutaneously implanted port-a-cath system. The infusion catheter is implaced into a side branch of the femoral artery as has previously not been described yet.

Method and Results

For the exposure of the femoral artery we prefer a longitudinal incision in the inguinal region. The femoral artery is then exposed up to the inguinal ligament. As a next step a suitable side branch of the artery is looked for and prepared. The arteria circumflexa ilium superficialis which is found running along the inguinal ligament to the superior spina iliaca anterior seems to fit this purpose as well as the superficial epigastric artery, which runs in the subcutis to the ventral abdominal wall[19].

After having prepared such an appropriate vessel the silicone catheter can be introduced into the lumen. In some cases a slight dilatation of the artery may be necessary to bring the tube in. In our opinion one's attention then has to be focused on the fact that the tip of the catheter is strictly placed shortly *before* and in no case *into* the main lumen of the femoral artery (Picture No. 1). The system is then filled with saline solution and shortened to the proper length in accordance to the final port position. The port itself is fixed by some sutures to the abdominal wall. Its correct function and intravasal position is controlled by punctioning the system with a saline-heparin filled syringe (as shown in Picture No. 2). We only use so called Huberneedles for punction purpose to assure a long life of the port-membrane[8]. The punction reservoir should not be placed into the belt line to prevent later mechanical irritations of the patient.

Up to now we have treated 4 patients with progressive stages of peripheral arterial occlusive disease through intermittent arterial Prostaglandin E_1 infusions via port systems with sufficient and encouraging clinical results. Rest pain could be significantly lowered except in one case. Two patients had been treated by hemodialysis for more than ten years showing severe diabetic disease in addition to arterial occlusion. In one of these two cases several toe amputations had been carried out over a period of two years without curing the defects.

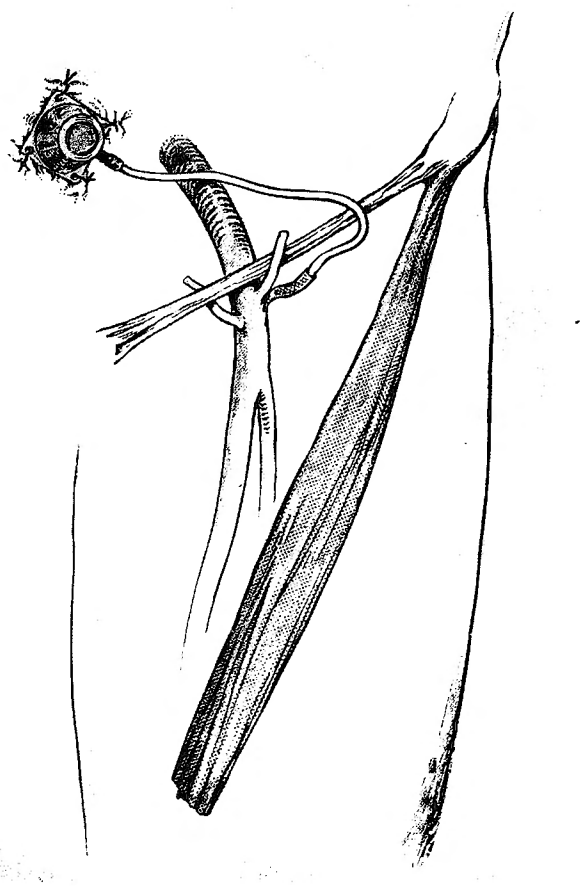

Fig. 1. The port system is subcutaneously placed and fixed on to the abdominal wall with appropriate sutures. The tip of the catheter is positioned directly before the main lumen of the femoral artery after its introduction through a side branch like the *arteria circumflexa ilium superficialis* or an other suitable side vessel and then stitched to the vasal wall to prevent dislocation.

After a three month period of intraarterial PGE_1 infusions the ulcer of the forefood could be healed and the patient has been without relapse for one year now. In no case further amputations after the continuous treatment had been necessary up to now (Table 1).

Discussion

The efficacy of intraarterially administered Prostaglandin E_1 as well as other vasodilating substances in stage III and IV of peripheral arterial vascular disease has been shown for many times in the literature[6,13,14,17], although the exact mechansims of action are not completely understood[2,15] Similar to Prostacyclin the Prostaglandin E_1 acts through a platelet-aggregation inhibiting effect besides the vasodilatation. This is mediated by direct relaxation of smooth

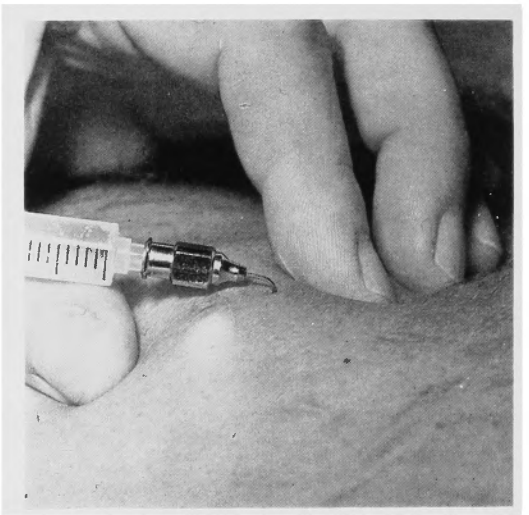

Fig. 2. The port is punctured with a Huber-needle to control the correct intravasal position of the catheter system and to rinse the system with heparine-saline solution after finishing the intraarterial perfusion.

Table 1. Clinical features of 4 patients with continuous intermittent intraarterial lower limb perfusion with Prostaglandin E_1

Case	age [Years]	Athero-sclerosis	Diabetes	Earlier amputations	Gangrene	Immediate effects of intraart. pge_1	Side effects
1	33	+++	+	+++	+	Disappearance of pain, healing of ulcer	0
2	58	+++	+	++	++	Ulcer healing, died 3 months later, renal failure, +after dialysis	0
3	77	++	−	−	−	Disappearance of pain	0
4	81	+++	−	−	+	No change	0

vascular muscles on the one hand[16] and stimulation of platelet-adenylat-cyclase on the other hand[20] The risk of undesired systemic side effects and complications is decreased because passing the lung capillary bed the substance is almost totally destroyed and inactivated[20].

These observations are confirmed by the clinical reports of a reduction of rest pain and lowered consumption of analgetics as well as the healing of ulcers. Further on an improvement of the Grade of Fontaine's classification, a fall of the rate of amputations or the possible preservation of a functioning limb and a shifitng of the amputation line further to the distal end if amputation is unavoidable are also ascribed to this kind of treatment[18]. However such therapies have to be repeated over a longer period of weeks and months, especially in the elderly patient. This almost inevitably implies the numerous disadvantages of the countless single arterial punctions. The main handicaps of this procedure are the additional unavoidable

mechanical vascular wall damage with eventually resulting arterial thrombosis or embolism, the increasing hematoma production after removal of the punction cannula, the risk of infection and the personal discomfort and pain of punction area felt by the patients.

The search for alternatives leads to the application of transcutaneously introduced intra-arterial catheters. This procedure provides only a comparatively short duration of possible treatment as it is not suitable for continual therapy over weeks or months due to the almost inevitable risk of infection or thrombosis. This calamity brought us to the invention of subcutaneously implanted port systems as a permanent arterial access. In central venous locations such systems have shown to be effective and elegant solutions for repeated administration of chemotherapeutics or for prolonged parenteral nutrition[8,9]. The indirect '*arterial*' punction can be done easily, quickly and safely. As an additional effect the cannulation itself is nearly painless for the patients. Compliance of repeated intraarteial drug application is significantly higher than in case of single punction maneuvers. The treatment can be performed in outpatients and does not deserve a longer stay in the hospital. The total hospital stay in chronic arterial occlusive disease patients may prospectively be shortened. Infections of the punction area are seldom when careful desinfection of this region precedes the cannulation[8]. After having completed the respective perfusion with an infusion pump we suggest rinsing the system with a heparin-saline solution before removing the needle. We believe that this will prevent a thrombosis of the catheter. In our experience it seems to be possible to perform continual arterial therapy over a period of several months and in some individual cases over years.

The subcutaneous port system also provides the possibility of intraarterial infusions of drugs other than the Prostaglandin E_1 described here, such as thrombolytic substances, heparin, antibiotics or other hemorrheological substances. This would imply a correspondingly wider spectrum of indications for this kind of therapy.

The direct implantation of the catheter into the main femoral artery lumen[11] can not be recommended because of the disadvantageously altered blood flow conditions under these circumstances. An arterial thrombosis or embolism could possibly arise from such a technique as a result of the altered hemodynamics. On the other hand the implacement of the catheter tip into a side branch immediately before the main femoral artery lumen does not alter the quality of femoral arterial blood flow as is suggested by our modification of arterial access. Although we did not install a non-return-valve into the distal tube part we did not see an adverse effect on catheter function up to now.

Conclusion

The new surgical approach of implanting a subcutaneously implaced port system into a side branch of the femoral artery for repeated intraarterial application of vasodilating or other pharmacological substances provides an easy and reliable type of permanent arterial access. Arterial punction can be performed quickly, safely and simply over a long period without a

considerable burden on the patient. Thus the technique lends itself as a method of choice to continuous repeated long term intraarterial administration of vasoactive or other drugs within the spectrum of therapeutic modalities of chronic peripheral arterial occlusive disease.

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